Quality and Patient Safety Issues in Surgical Pathology and Cytopathology

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I would like to begin by acknowledging that I am on the traditional lands, referred to as Treaty 6 Territory and that the City of Saskatoon and all the people here are beneficiaries of this peace and friendship treaty.

Objectives

- Describe the basic elements of quality assurance
- Describe the stages of test cycle monitoring
- Name ADASP* recommendations for quality assurance
- Name the Canadian QA guidelines for interpretative pathology
- Develop an organized approach to practical quality and patient safety issues pertaining to surgical and cytopathology

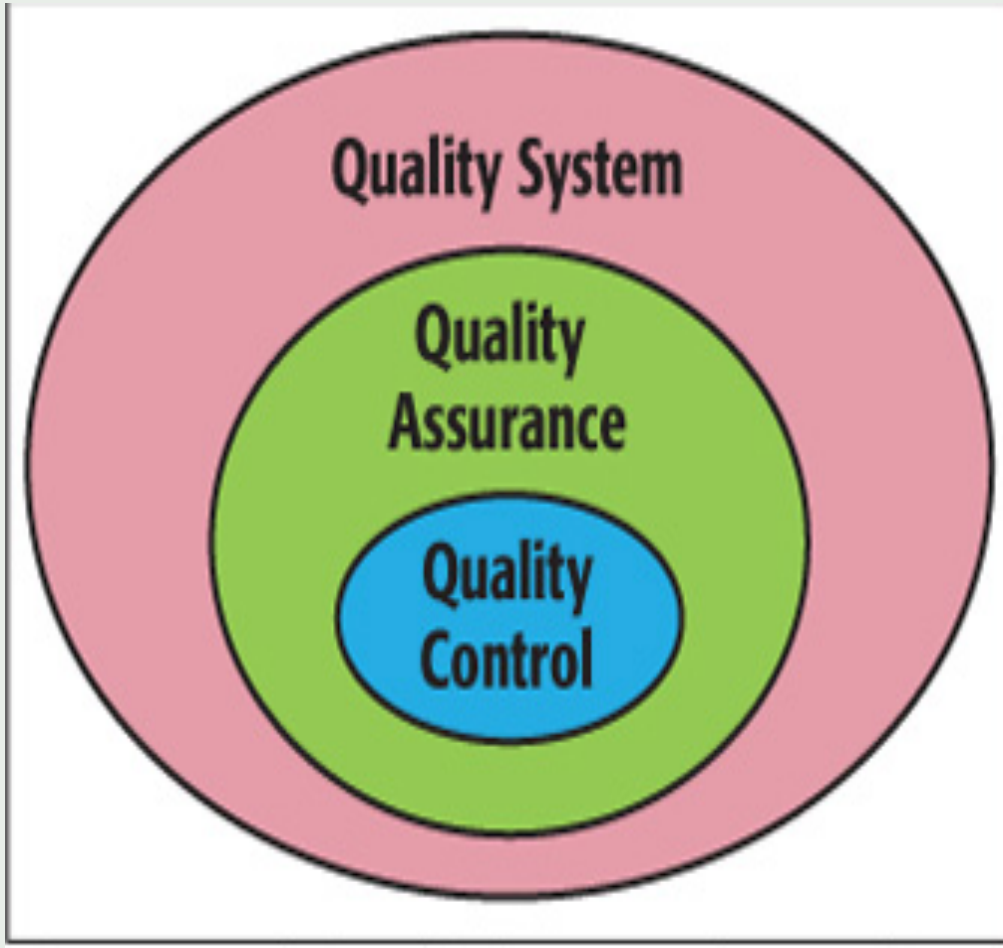
*ADASP=**A**ssociation of **D**irectors of **A**natomical and **S**urgical **P**athology

Examination prep

- Be familiar with QA basics, test cycle monitoring
- General recommendations for accreditation
- Laboratory safety, infection control, retention of slides/blocks guidelines, critical values….
- Practice working through scenarios of problems that can arise
  - *Practice formulating an* ***organized approach***

Terminology

- **Quality improvement/management:** systematic and formal approach to the analysis of practice performance and efforts to **improve quality performance**
- **Quality Assurance:** program that ensures the **final result** reported is as correct and accurate as possible (proactive, ongoing, comprehensive process/during)
- **Quality Control:** tools/measures included in every test to help **detect and correct defects** in the system (reactive process/after)



Quality and patient safety in pathology

- **Culture** of transparency, safety, preoccupation with failure
- **Reliability and accuracy** in all parts of the test cycle- not just analytic phase
- Reactive and proactive **tools**
  - *Report non-compliant events via a secure tracking system*
  - *Allows for corrective measures (quality control)*
- Robust and timely **analysis and follow-up** of errors/events

Quality and patient safety in pathology

- Quality
  - *Monitoring all phases of test cycle*
  - *Technology: dashboards*
  - *Quality improvement and workflow design*

- Patient safety
  - *Root cause analysis*
  - *M&M/QA rounds*
  - *Incident and near miss review*

Measuring quality in surgical pathology

- Common measures:
  - *Accuracy, timeliness, completeness of reports*
- Categories of 5 monitors commonly used:
  - *Pre-analytic*
  - *Analytic*
  - *Post-analytic phases*
  - *Turn-around-time (TAT)*
  - *Clinician satisfaction and/or complaints*

1. Pre-analytic phase monitors

- Specimen fixation
- Specimen delivery, lost specimens
- Specimen identification
  - *Require stringent labeling standards*
  - *If a specimen is received without appropriate documentation, the submitting clinician must be contacted before accessioning*
- Adequacy of clinical history
  - *Affects accuracy and completeness of reports*
- Accessioning errors

2. Analytic phase

- Begins with gross examination, ends with diagnosis
- Rendering of a diagnosis (most critical)
- Accuracy of the final diagnosis relies on the effectiveness of all these sequential steps

2. Analytic phase monitors

- Intraoperative assessment errors
  - *FS- permanent section concordance*
- Failure to preserve tissue in appropriate fixative or for ancillary studies
- Grossing errors, omissions
- Histologic monitors
  - *Specimens lost in processing*
  - *Block labeling*
  - *Slide labelling*
  - *Quality of histologic sections*
  - *Histology TAT*
  - *Extraneous tissue*
- Final diagnosis
  - *peer review error rate*

Analytic phase monitors cont'd

- Immunohistochemistry
  - *Frequency and cause of repeat stains*
  - *TAT*
  - *Report audit for integration of stains into report*
  - *Annual review of antibody inventory*
  - *EQA*
- Molecular studies
  - *TAT*
  - *EQA*

Specimen identification

- The tissue **must** correspond to the site biopsied
- Clinical descriptors and setting **must** correlate
- **If there is a discordance**, consider the possibility of a misidentified specimen
  - *Discuss with clinician*
  - *Review process for similar cases handled on the same day*
  - *May require identity testing*
  - *If a clinician questions a diagnosis, the possibility of an error must be addressed*
  - *Involve departmental QA officer, if available*

Gross examination

- Must provide supervision/feedback for residents, PAs
  - *Appropriate sampling, adherence to **protocols***
- Advances in imaging modalities have resulted the identification of **smaller tumors**
  - *Specimen radiography, review of imaging, consultation with radiologist*
- Reexamination of large specimens
  - *Discordance with prior biopsy, insufficient sampling, LN retrieval, radiographic findings not concordant*

Microscopic assessment

- Routine checks for each case:
  - *Patient's name, ID, bar code scan*
  - *Match all components: H&E, IHC, flow cytometry*
  - *Completeness of case*
  - *Clinical history, imaging*
  - *Do the findings make biologic sense?*
  - *Is the diagnosis unexpected?*

Microscopy: accurate diagnosis

- Sources of error:
  - ***Failure*** *to assess entire slide, case*
  - ***Failure*** *to recognize a diagnostic entity, know one's limitations*
    - Maintain CME, consult colleagues, subspecialty experts
    - This type of error is generally rare (<1% of cases)
- Standardize diagnostic criteria and terms (up to date)
- Clinical correlation
- Ancillary studies
- **Seek help with diagnostically difficult cases**

Case reviews/peer review

- Main method used to prevent/detect cognitive error
- Focused internal double read of specialized cases (i.e. brain tumors, esophageal dysplasia, positive/suspicious cytopathology…)
- Unusual or rare diagnoses
- Cases out of scope of practice

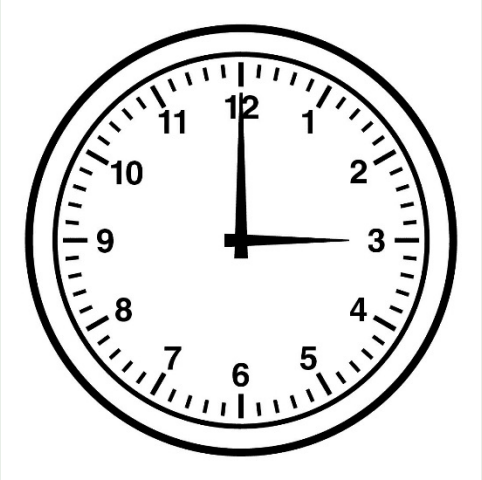
Peer review

- Random % review
- Focused internal review (e.g. specific biopsy types)
- Interdepartmental conferences (tumor boards)
- Intradepartmental QA conference
- FS/permanent section correlation
- Cytology/histopathology correlation
- Review of previous pathology material
- Intradepartmental review before release to other institutions
- Review of outside diagnoses
- Overall peer review rate and error rate

3. Post-analytic phase

- Transcription errors
- Verification errors during sign out or report finalization
- Report delivery errors (including transmission of critical values, changes issued in amended reports)
- Incomplete reports
  - *Utilization of standardized synoptic templates*
- Incomplete/lack of correlation of diagnosis with ancillary studies
- Poor/confusing report formatting
- Failure of the clinician to understand the report

4. Turn around time (TAT)



- TAT important measure by which laboratory performance is judged
  - *Frozen section*
  - *Biopsy*
  - *Large specimen*
  - *Preliminary and final autopsy reports*

5. Clinician satisfaction and/or complaints

- Overall satisfaction
- Diagnostic accuracy
- FS timeliness/accuracy
- Report timeliness
- Report completeness
- Pathologist availability
- Feedback for recent changes

Structural components

- Work force
  - *Flexible, well-trained knowledgeable staff*
  - *Appropriate qualifications*
  - *Redundancies in skills*
  - *Teamwork*

Structural components

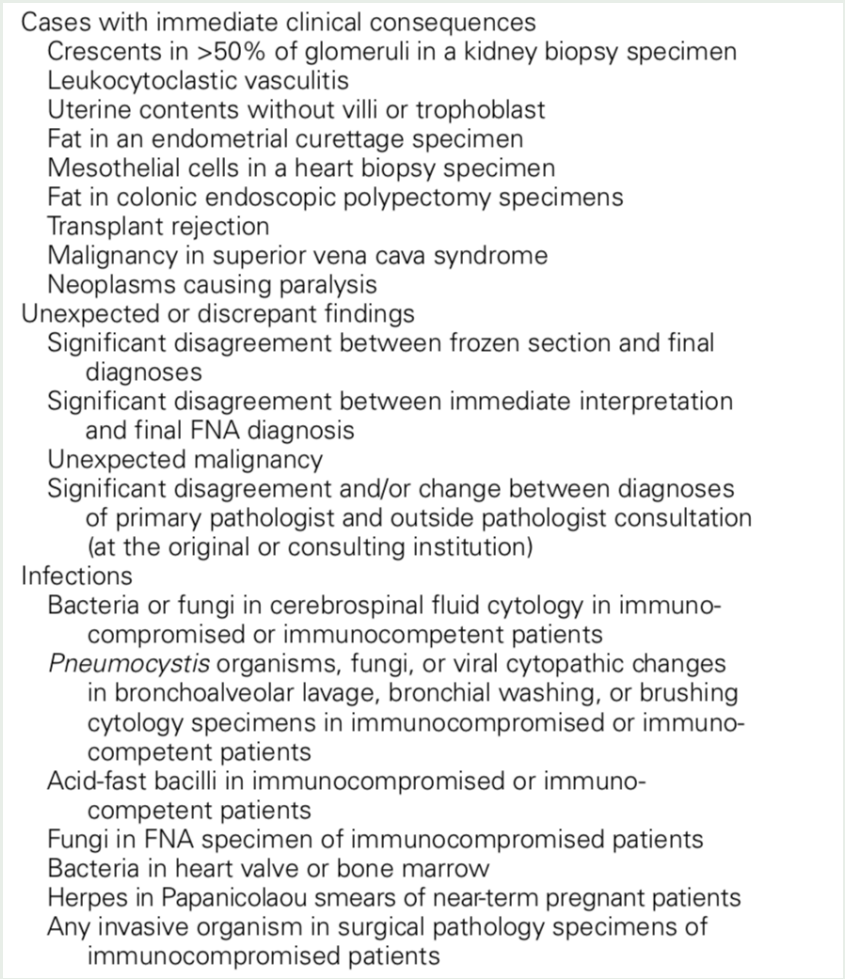
- Continuous education and training
- Comprehensive computer system
  - *Labeling, bar-coding and tracking mechanisms*
- Standardized tasks and language
  - *SOP's*
- Ability to change and adapt
- Resources to permit regulatory compliance

Communications

- Urgent or unexpected results (critical value)
- Intraoperative consultation
- Multidisciplinary conference

Unexpected diagnosis/critical value

- Know which diagnoses are ‘critical’
- Contact the clinician directly/Document details of the communication in your report



Cases with immediate clinical consequences
- Crescents in >50% of glomeruli in a kidney biopsy specimen
- Leukocytoclastic vasculitis
- Uterine contents without villi or trophoblast
- Fat in an endometrial curettage specimen
- Mesothelial cells in a heart biopsy specimen
- Fat in colonic endoscopic polypectomy specimens
- Transplant rejection
- Malignancy in superior vena cava syndrome
- Neoplasms causing paralysis

Unexpected or discrepant findings
- Significant disagreement between frozen section and final diagnoses
- Significant disagreement between immediate interpretation and final FNA diagnosis
- Unexpected malignancy
- Significant disagreement and/or change between diagnoses of primary pathologist and outside pathologist consultation (at the original or consulting institution)

Infections
- Bacteria or fungi in cerebrospinal fluid cytology in immuno-compromised or immunocompetent patients
- *Pneumocystis* organisms, fungi, or viral cytopathic changes in bronchoalveolar lavage, bronchial washing, or brushing cytology specimens in immunocompromised or immuno-competent patients
- Acid-fast bacilli in immunocompromised or immuno-competent patients
- Fungi in FNA specimen of immunocompromised patients
- Bacteria in heart valve or bone marrow
- Herpes in Papanicolaou smears of near-term pregnant patients
- Any invasive organism in surgical pathology specimens of immunocompromised patients

Association of Directors of Anatomic and Surgical Pathology. Critical diagnoses (critical values) in anatomic pathology. *Am J Clin Pathol* 2006;125:815-817.

Intraoperative consultation

- Review OR schedule
- Look up clinic notes, imaging in EMR
- Speak directly to surgeon if the clinical question is not clear
- Anticipate problems (infection, small specimen, FS pitfalls)
- Verbal report: patient identifiers, organ/tissue, listen when diagnosis is relayed, document report, ask if anything further is needed
- If permanent-FS discrepancies occur, communicate directly with the surgeon as soon as possible (‘critical value’)

Multidisciplinary conference

Improved patient outcome
(Reduced wait times between diagnosis, evaluation and treatment; reduced error and injury rates; reduced medication orders, cost and reduced mortality)

More accurate treatment recommendations, multidisciplinary evaluations and adherence to guidelines

Greater satisfaction of care providers (peer support, education)

The Association of Directors of Anatomic and Surgical Pathology

- ADASP, founded in 1989
- Membership: directors of AP/SP laboratories from academic centres, US, Canada, international

- Association of Directors of Surgical Pathology. Recommendations for quality assurance and improvement in surgical and autopsy pathology. *Human Pathology* 2006;37(8):985-988.

General Recommendations

1. *Departmental QA and improvement plan*
   - Annual Plan to monitor quality with specific aims for each year
2. *QI Committee*
3. *QA & QI monitors (at least one in each of five sections):*
   - Preanalytic
   - Analytic
   - Post analytic
   - TAT
   - Clinician satisfaction

General Recommendations

4. Quality assurance case reviews

- Review of percentage of cases
- Focused internal second review of specific organ or malignancy type
- Interdepartmental conferences (tumor boards)
- Intradepartmental QA conferences
- Frozen section/permanent section correlations
- Cytology /surgical pathology correlations
- Review of previous pathology material
- Intradepartmental review prior to release to other institutions
- Review of outside diagnosis of in-house cases

General Recommendations

5. Defining error types and quantification of effect on patients
   - Error types
     - Categorical interpretation (benign to malignant)
     - Change in same category (type of malignancy)
     - Change in threshold (ADH vs DCIS)
     - Change in margin status
     - Change in lymph node status
     - Change in information unrelated to diagnosis
     - Case or patient misidentification
     - Site misidentification (right /left)

General Recommendations

- **Effect on patient**
  - *No harm*
  - *Slight harm*
  - *Significant harm*

General Recommendations

6. Error correction
   - *Change in diagnosis – amended report*
   - *Change of information other than diagnosis – corrected report*
   - *Additional information – addendum report*

General Recommendations

7. TAT

8. Sentinel event (incident with significant patient harm, breach of procedures/policies)

9. Pathologist competency

    TAT

    Frozen section/permanent section concordance rates

    Diagnostic error rate

    Clinical complaints/satisfaction

ADASP QC/QA Indicators

- **Intraoperative consultation**
  - *Regular audits*
    - *Agreement*
    - *Deferral – appropriate*
    - ***Deferral – inappropriate (10%)***
    - *Disagreement – minor*
    - ***Disagreement – major (<3%)***
  - *TAT (20 min for single block)*

ADASP QC/QA Indicators

- Inte**rinstitutional review**
  - ***Must record external opinion in the report and compare with the original diagnosis***
  - *Acceptable threshold for clinically significant disagreement following arbitration is 2%*

ADASP QC/QA Indicators

- **SP TATs**, in working days

Specimen type	Verbal report (days)	Written report (days)
Rush case	1	2
Biopsies	2	3
Surgicals	2	3

- Extra time for fixation, decal, recuts, IHC etc.
- Acceptable threshold for TAT is 80%

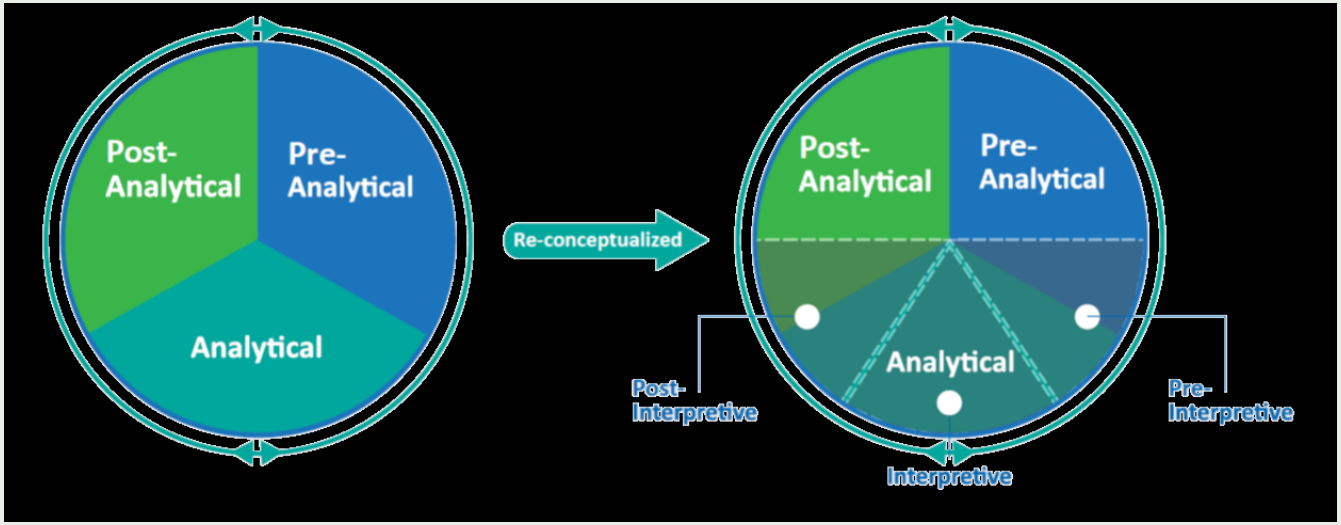
ADASP QC/QA Indicators

- Autopsy TAT
  - *Provisional report: 1 day (90% of cases)*
  - *Final report: 30 days (80% of cases)*
- Lost specimen
  - ***Irretrievable loss of SP specimen after accessioning: < 1/3,000 cases***

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology (Nov 2016)

- Lab medicine is a leader in patient safety, quality assurance and quality improvement for >50 yrs
- Technical, clerical and administrative aspects of the system are well understood and regulated
- Quality systems governing **interpretive aspects** (AP and related disciplines) are less well developed and standardized
- Quality Initiative in Interpretive Pathology (QIIP) – reconceptualizes pathology test cycle – pathologist is a medical practitioner

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology



Based on Quality Initiative in Interpretative Pathology Project (QIIP) (CPAC and CAP-ACP partnership)

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

- **Foundational elements**
  - *Governance –Jurisdictional*
  - *Governance- Institutional*
  - *Linkage to existing QA programs*
  - *Human resources/workload/staffing*
  - *Appropriate training/licensure/credentialling*
  - *Continued professional development*
  - *Privacy, confidentiality, disclosure and duty to report*
  - *Informatics and quality documentation system*
  - *Other foundational resources*

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

Pre -Interpretive

- specimens exempt from submission to lab/gross only
- measures for minimizing mix up (bar coding)
- who can gross specimens
- ID and clinical information verified
- assessment of quality of technical preparation

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

Diagnostic

- done by pathologist
- correlation of clinical information
- access and use of additional studies as needed
- prospective and or retrospective peer review

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

Post interpretive

- reconfirm patient id
- check accuracy and completeness of report
- timeliness of report
- report delivery

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

Policies and Procedures

- *Intradepartmental consultation*
- *Intraoperative consultation*
- *Internal correlative activities*
- *Internal retrospective reviews/audits*
- *External consultation*
- *External reviews*

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

- **Policies and Procedures cont.**
  - *Urgent diagnosis and significant and unexpected findings*
  - *Revised (addended, amended reports)*
  - *TAT*
  - *Completeness of reporting*
  - *Onboarding Pathologist performance assessment*
  - *Service satisfaction*

Pan-Canadian Quality Assurance Recommendations for Interpretative Pathology

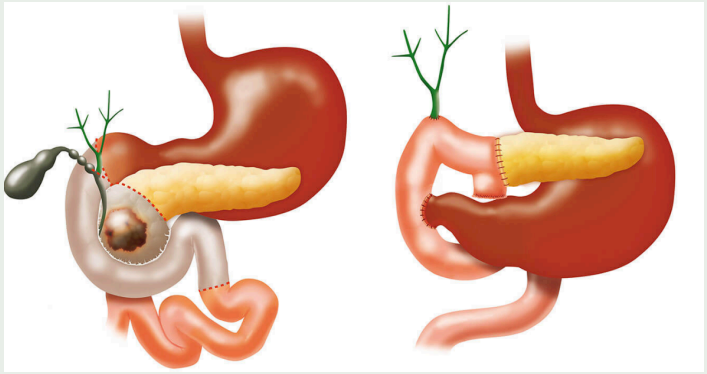
- External Quality Assurance
  - *External Quality Assessment*
  - *Pathologist Peer Review Assessment*

- Approach to “Expression of Concern” regarding a Pathologist’s Performance

Case examples

- *Discordant diagnosis*
- *Clinician complaint, quality indicator monitoring*
- *Introducing a new test*
- *Improving a QA program*
- *Missing specimen*
- *Discordant IHC results*
- *Systemic problem*

Case 1



- You are reviewing a Whipple's resection case from a 70 year old male; you see chronic pancreatitis but no malignancy.
  - *What do you do?*

Case 1: Missing cancer

- Scenario 1:
  - *You review the previous needle biopsy and disagree with the interpretation; you think there is reactive atypia but not definite malignancy.*
    - What do you do?

Case 1: Missing cancer

- Scenario 1: potential interpretative error (analytic phase)
- Review case with responsible colleague, reach consensus
  - *Consider additional studies (IHC?), external consult*
- Review with Division Head
- Assuming the biopsy is now deemed benign:
  - *Notify clinicians verbally, issue an amended report and document notification details*
  - *Notify risk management; patient disclosure*
  - *Report the incident via institutional electronic patient safety system*
  - *Incident review, root cause analysis*

Case 1: Missing cancer

- Scenario 2
  - *You agree with the original diagnosis – positive for adenocarcinoma*
  - *What should you consider?*

Case 1: Missing cancer

- ‘Vanishing cancer’
  - False positive biopsy (excluded in this case)
  - Pre-analytic phase errors
    - *Specimen mix-up*
  - Analytic phase errors
    - *Specimen mix-up/ ‘floater’ on cell block*
    - *Identity testing*
  - False negative Whipple’s resection
    - *Cancer remaining in blocks: levels; re-embed, flip tissue blocks*
    - *Cancer lost by trimming blocks*
  - ‘Therapeutic ’ biopsy
  - Cancer altered by neoadjuvant treatment effects, inflammation

Case 2

- A surgeon at your institution complains that she is encountering too many discrepant FS reports, and that the TAT is too long. You are on the AP QA committee and are tasked with addressing her concerns. What do you do?

Case 2: Quality indicator audit

- Contact the surgeon
  - *Are there specific cases of concern?*
  - *Specific types of cases, individual staff involved, unrealistic expectations?*
- FS audits:
  - *ADASP benchmarks/review your institutional benchmarks*
    - % Disagreement-major
    - % Deferral-inappropriate
    - TAT

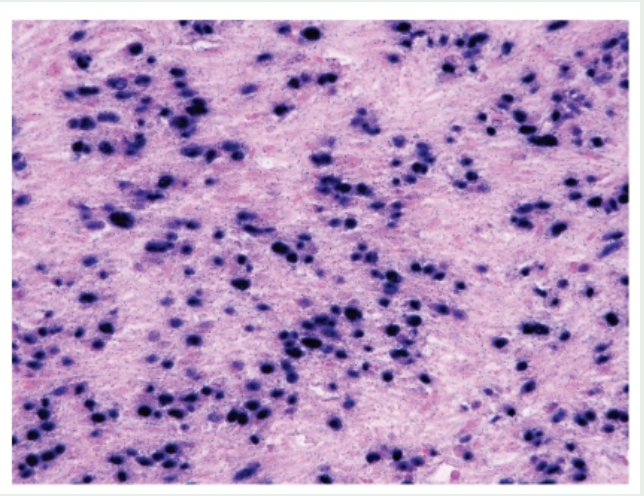
Case 2: Quality indicator audit

- Use LIS to perform the audits
- Review FS slides to determine category
  - *Benchmark indicators overall*
  - *Benchmark indicators/pathologist*
- If there is a deviation from a benchmark, what is the cause?
  - Interpretation; difficult to classify lesions
  - Block or specimen sampling
  - Technical inadequacy
  - Lack of clinical or pathologic data

Case 2: Quality indicator audit

- TAT problem: what is the source?
  - *Porter system, insufficient technical staffing, technology, unreasonable expectations*
- Follow-up
  - *Include findings in Annual QA report*
  - *Present data at QA rounds*
  - *Targeted CME for pathologists with knowledge gaps*
    - Employ technology to allow for second FS opinions
  - *Address technical staffing/performance issues*
  - *Address the complaints with appropriate colleagues*
  - *FS audits should be routine (q 6 months)*

Case 3



- Your Division Head has asked you to help develop a new test for your laboratory: Epstein Barr virus encoded RNA in situ hybridization (EBER)
- What steps should you take?

Case 3: Introducing a new test

- 1. Is this a clinically useful test in your centre?
- 2. Cost of performing in-house vs. referring out
- 3. Expected volume of tests
- 4. Appropriate platform for test?
- 5. Do you have the appropriate materials for validation?
- Contact a laboratory currently performing the test for support

Case 3: Introducing a new test

- Select appropriate commercial probe for your platform (LDT vs commercial kit)
- Validation (20 positive + 20 negative cases; ≥ 90% concordance)
- External ‘on slide’ controls (positive and negative) with EBER positive probe
  - *Separate RNA (oligo-dT) positive control probe slide to show integrity of tissue RNA*
  - *Separate EBER negative reagent control*
- Training: technical, interpretive
- EQA

Case 4: Expanding/improving a QA plan

- You have agreed to serve as the Medical Director for Cytopathology in your laboratory. You believe the QA initiatives for the gynecologic cytopathology service are insufficient.
- What should you do?

Case 4: Expanding/improving a QA plan

- Consult resources: ADASP, CSC guidelines
- QA&I committee
- Align with Departmental QA&I plan
- Monitor indicators: test cycle variables, **workload monitoring**
- Annual Cytopathology QA report

Case 4: Expanding/improving a QA plan

- Gynecologic cytology service: Analytic phase
- Review a proportion of slides for technical quality daily
- Rescreening/prescreening for negative paps
  - *Prospective: targeted (high risk), random (10%),* ***rapid (100%)***
  - *Retrospective: all negative paps x 3 yrs rescreened following new ASCH dx or higher*
- Work-load standards
- Policies for reporting alert/critical diagnoses

Case 4: Expanding/improving a QA plan

- Gynecologic cytology service: Post-analytic phase
- Slide/requisition retention policies
- Tissue correlation
- Peer review: consensus review, internal QA opinions
- External proficiency programs
- Performance indicators

Case 4: Expanding/improving a QA plan

- **Performance indicators** (lab, pathologist, cytotechnologist)
  - *Unsatisfactory specimen rate (and for providers)*
  - *Rates of each major Gyne diagnosis*
    - ASC:SIL ratio (Bethesda benchmark: ≤ 3:1)
  - *TAT*
  - *Discrepancy rate (tissue correlation, cytotech/pathologist)*
  - *False negative rate*
  - *Workload*
  - *Corrected/amended reports*
  - *Second opinions; monitor discrepancies between opinions*

Case 5

- A thoracic surgeon has called your laboratory looking for results for a transbronchial biopsy
  - *Is there a record of the specimen in the LIS?*
  - *What could have happened?*
  - *What do you do?*

Case 5: Missing specimen

- Possible scenarios (no record in LIS):
  - *Similar specimens were received on the same day and one was mislabeled*
  - *Patient's name was incorrect and case has been accessioned under an incorrect name (e.g. patient's first name)*
  - *Specimen is elsewhere in the hospital, another section of the lab*
  - *Specimen was included with another specimen from the same patient*
  - *Specimen was transported to the wrong institution*

Case 5: Missing specimen

- Obtain details of the case
  - *Patient identifiers*
  - *Date, time, location of procedure*
  - *Were other specimens for this patient obtained for other purposes (e.g. microbiology?)*
  - *How was the specimen transported (porter service records)*

Case 5: Missing specimen

- Obtain a list of all patients biopsied from the same site that day
- Obtain list of all cases accessioned in the lab that day
- Check porter case list
  - *Was specimen sent elsewhere?*

Case 5: Missing specimen

- May need to systematically review all cases received from the OR suite from that day
- May need to perform identify testing if there is suspicion that the specimen was accessioned under the wrong patient name
- Must report incident to risk management
- Must try to determine the source of the error
- Review/improve SOP's to prevent the incident from recurring
- Report the incident via institutional electronic patient safety system

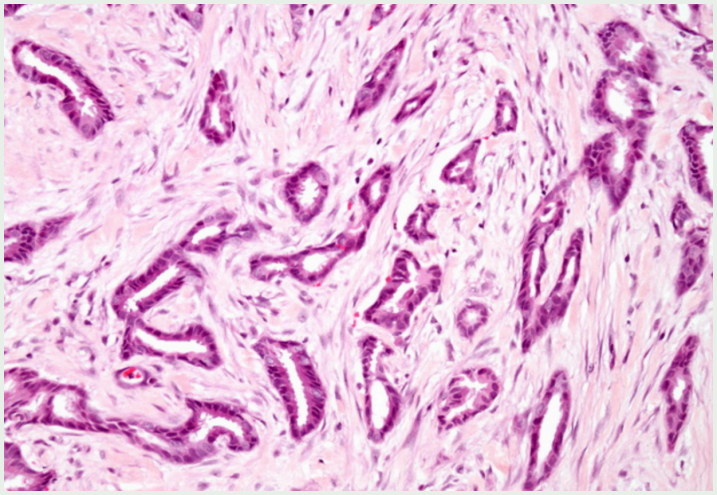
Case 5: Missing specimen

- Other scenarios (record in LIS)
  - *Empty container*
    - Check container, lid, workspace carefully
    - Check other containers for the same patient
    - If specimen cannot be found, the clinician must be contacted the same day; document communications
    - Report the incident via institutional electronic patient safety system

Case 5: Missing specimen

- Other scenarios (record in LIS)
  - *Specimen is lost in the laboratory*
    - Case set aside for infection precaution
    - Specimen is in a waste container
      - *Save containers for at least one extra day*
    - Tiny specimen was dropped during grossing
    - Tissue lost during processing: cassette not properly closed, small specimen not wrapped
    - Tissue lost during embedding

Case 6



- You are reviewing the biomarker IHC for a case of invasive tubular carcinoma, Nottingham grade 1. The ER IHC is negative.
  - *Is this a problem?*
  - *What do you do?*

Case 6: Discordant IHC result

- Review the H&E to confirm tumor type/grade
- Check internal/external controls
- Consider the pre-analytic, analytic variables that may cause false negative IHC
  - *Pre-analytic variables: fixative, cold ischemic time, fixation duration, decal, cautery, etc*
  - *Analytic variables:*
    - Problem with the IHC run (reagents depleted/expired, platform technical problem)?
    - Diagnostic error: MGA, adenoid cystic carcinoma, metastasis…
- Repeat on another block/specimen
- Refer out for repeat testing

Case 7

- You are in charge of your AP laboratory. One of the tissue processors was accidentally misprogrammed and most of the tissue blocks/biopsies are damaged and difficult to interpret.
  - *What do you do?*

Case 7: System problem

- Obtain list of cases, patients affected
- Assemble colleagues to review each case and identify which cases are irretrievable/not interpretable
- Notify risk management, Department Head
- Notify clinicians
- Formulate a summary of the issue to append to reports for each case

Case 7: System problem

- Determine the source of the error
- Review/improve SOP's to prevent the incident from recurring
- Report the incident via institutional electronic patient safety system

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thank you
danke
gracias
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謝謝
ngiyabonga
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go raibh maith agat
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takk
taiku
sagolun
hvala
mauruuru
мерси
감사합니다
ありがとう
ευχαριστώ
рахмат
Баярлалаа
faafetai lava
mersi
barka
welalin
tack
spas
vinaka
blagodaram
спасибі
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
obrigada
murakoze
chokrane
mamnun
djiere dieuf
tau
дякую
sulpay
gratias ago
gràcies
chnorakaloutioun
dankon
akun
köszönöm
kiitos
dankie
dhanyavad
nanni
nandri
bayarlalaa
gràcie
enkosi
sobodi
dêkuji
mèsi
madloba
najis tuke
kam sah hamnida
rahmat
rahmet
tanemirt
diolch
dhanyavadagalu
shukriya
trugarez
xiexie